UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 0:18-cv-61047-UU

UNITED STATES OF AMERICA,

Plaintiff,

v.

US STEM CELL CLINIC, LLC, *et al*.,

Defendants.
_____/

ORDER

THIS CAUSE is before the Court upon Defendants' Motion to Clarify and to Stay the Requirement that Patient Cells Currently Stored in an FDA-Registered Tissue Bank be Destroyed (the "Motion"). D.E. 207. The Court has reviewed the Motion and the pertinent portions of the record and is otherwise fully advised in the premises.

On June 3, 2019, the Court granted summary judgment in favor of Plaintiff, the United States of America. D.E. 73. In that order, the Court agreed with the FDA that Defendants' stromal vascular fraction product ("SVF Product") was an adulterated and misbranded drug under the Food Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et. seq*. *See* D.E. 73 at 28-30. Consequently, on June 25, 2019, the Court entered an injunction (the "Order of Permanent Injunction"), which, *inter alia*¸ enjoins Defendants from manufacturing and/or providing any services relating to its SVF product and requires Defendants to destroy all SVF Product currently in their possession, custody, or control. D.E. 83 at 9 ¶ 10. In the instant Motion, Defendants request that the Court modify the injunction to stay the destruction of the SVF Product because, *inter alia*, the patients who provided their stem cells have a property right in the SVF Product.

As an initial matter, the Court is not persuaded that any party has a property interest in the SVF Product warranting a stay of the Order of Permanent Injunction. First, the law is unsettled as to a party's rights in its biological tissue. *See, e.g., Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1075 (S.D. Fla. 2003) (explaining that "[t]he property right in blood and tissue samples also evaporates once the sample is voluntarily given to a third party."). And, in this case, any such rights would be governed by the contractual relationship between Defendants and each individual patient, which rights are not addressed properly in this lawsuit. Second, as explained in the Court's Order on the Parties' Motions for Summary Judgment, the SVF Product is not the same as the patients' stem cells; rather, the SVF Product is a separate product created by Defendants through a proprietary and complex multi-step processing procedure. *See* D.E. 73. Lastly, in-line with well-settled and recently affirmed Supreme Court precedent, in the Court's Order on the Parties' Motions for Summary Judgment, the Court deferred to the FDA's scientific expertise and its interpretation of the FDCA that the SVF Product is an adulterated and misbranded drug. *See* D.E. 73; *Kisor v. Wilkie*, 139 S. Ct. 2400 (2019) (affirming *Auer v. Robbins*, 519 U.S. 452 (1997)). Accordingly, the Court is not persuaded that any party has a property interest in the SVF Product because it is an adulterated and misbranded drug. *See United States v. Ellis Research Labs., Inc.*, 300 F.2d 550, 554 (7th Cir. 1962) ("We find no merit in defendants' argument that the injunction sought and granted is an unconstitutional and unwarranted exercise of the regulatory powers exercised by the United States under the Act in question . . . <u>they can have no vested interest in a business activity found to be illegal</u>.") (emphasis added).

Nevertheless, the Court recognizes that pursuant to Federal Rule of Appellate Procedure 4, Defendants have sixty (60) days from the date of entry, June 25, 2019, to appeal this Court's Order of Permanent Injunction, including the portion requiring the destruction of Defendants' SVF

Product, and the underlying summary judgment order. Fed. R. App. P. (4)(a)(1)(B). As the United States does not oppose a stay of the provisions requiring destruction of the SVF product, the Court will amend the injunction to require the destruction of the SVF Product once the expiration of the deadline to file a notice of appeal has passed, or if Defendants choose to appeal, once the Eleventh Circuit Court of Appeals issues its mandate with respect to the appeal. *See* D.E. 225. However, the Court will also impose minimal safeguards consistent with the terms of the Injunction and the Court's Order on the Parties' Motions for Summary Judgment to ensure the appropriate preservation and disposition of the SVF Product. Defendants have been notified of the proposed terms and have not expressed any substantial disagreement with their imposition. *See* D.E. 231. Accordingly, it is

ORDERED AND ADJUDGED that the Motion, D.E. 207, is GRANTED IN PART and DENIED IN PART. The Order of Permanent Injunction, D.E. 83, is HEREBY AMENDED IN PART as follows:

(1) Paragraph 10 SHALL NOW READ:

> 10. Within thirty (30) calendar days after: (1) the expiration of the deadline to timely file a Notice of Appeal of this Court's Order of Permanent Injunction pursuant to Federal Rule of Appellate Procedure 4; or (2) if Defendants timely file a Notice of Appeal of this Order of Permanent Injunction pursuant to Federal Rule of Appellate Procedure 4, the issuance of a mandate as to such appeal from the United States Court of Appeals for the Eleventh Circuit pursuant to Federal Rule of Appellate Procedure 41, Defendants, under FDA's supervision, shall destroy any and all SVF Product that is in Defendants' possession, custody, or control. Defendants shall bear the costs of destruction and the costs of FDA's supervision.

Defendants shall not dispose of any SVF Product in a manner contrary to the provisions of the Act, any other federal law, or the laws of any state or territory, as defined in the Act, in which the drugs are disposed.

(2) The Court INSERTS a NEW PARAGRAPH 10(A), WHICH SHALL READ:

A. If Defendants appeal this Order of Permanent Injunction to the United States Court of Appeals for the Eleventh Circuit, until the issuance of a mandate as to such appeal pursuant to Federal Rule of Appellate Procedure 41, Defendants shall place a conspicuous label on the articles or place a sign in a conspicuous manner in all locations where any SVF Product is stored stating that the articles must not be used, moved, altered, or tampered with in any manner pursuant to Order of the United States District Court for the Southern District of Florida.

(3) The Court INSERTS A NEW PARAGRAPH 27, which SHALL READ:

27. By August 19, 2019, Defendants shall submit to the United States and this Court an accurate and current inventory of any and all articles containing SVF in their possession, custody, or control (whether or not Defendants recovered the tissue used to manufacture the SVF Product). Such inventory shall include, at a minimum, a detailed description of where those articles are being held; how and where those articles were manufactured within the meaning of 21 C.F.R. § 1271.3(e).

ALL OTHER TERMS OF THE ORDER OF PERMANENT INJUNCTION, D.E. 83, REMAIN IN FULL FORCE AND EFFECT, INCLUDING DURING THE PENDENCY OF ANY APPEAL OF THE ORDER OF PERMANENT INJUNCTION.

DONE and ORDERED in chambers at Miami, Florida, this _19th_ day of July, 2019.

URSULA UNGARO
UNITED STATES DISTRICT COURT JUDGE

Cc: All Counsel of Record